For more information about indications, contraindications, warnings and instructions for the Express® LD Iliac Premounted Stent System, visit **www.bostonscientific.com**.

You can also call Boston Scientific customer service at **1.888.272.1001** to request copies of the Directions for Use (DFU).

CAUTION: Federal (USA) law restricts these products to sale by or on the order of a doctor.

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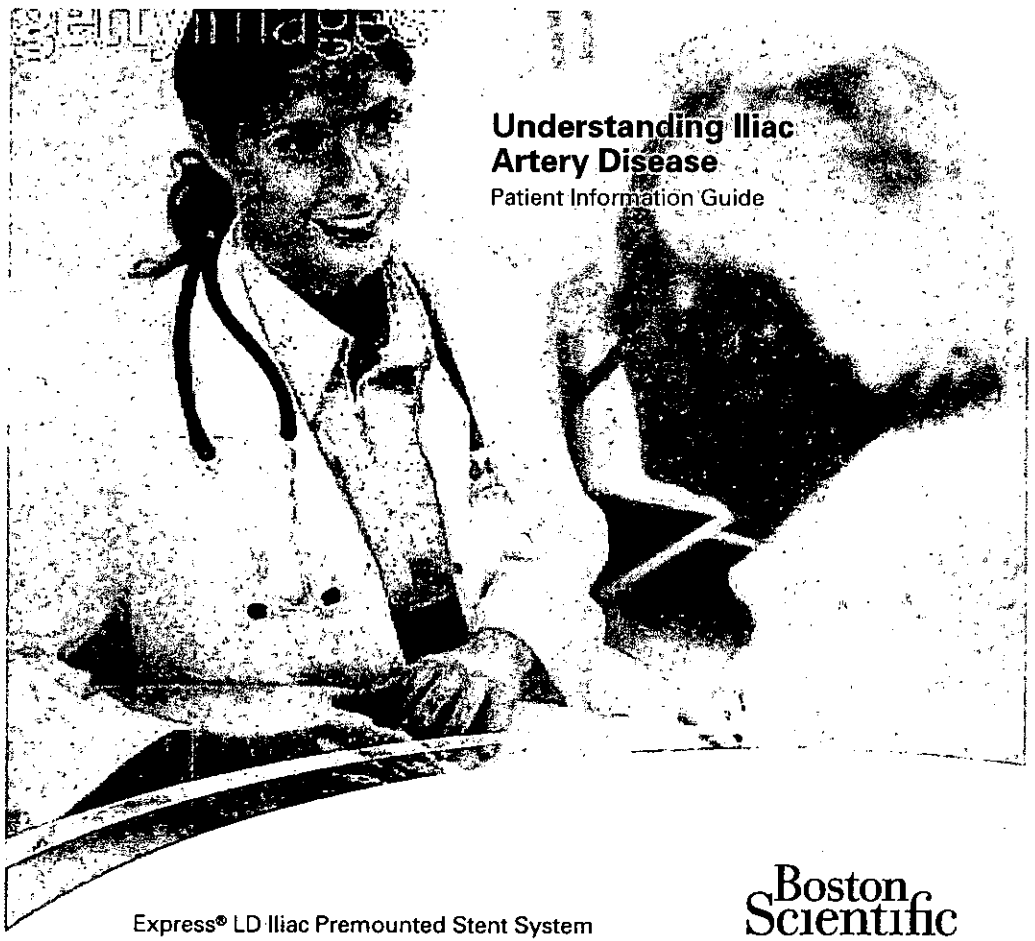

Understanding Iliac Artery Disease

Patient Information Guide

Express® LD Iliac Premounted Stent System

Boston Scientific

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Table of Contents

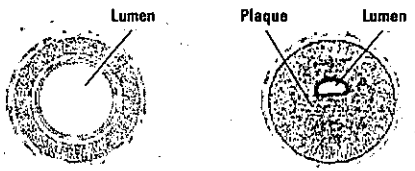
Treating iliac artery disease

Your doctor wants you to have a stent placed in your iliac artery. This is to help treat your iliac artery disease. This guide explains the procedure and what you can expect from start to finish. A glossary at the end of this guide defines common medical terms about this procedure.

You will also learn steps you can take to live a healthier life with iliac artery disease.

What is iliac artery disease?

Iliac artery disease is caused by the narrowing of the arteries leading to the legs. This narrowing can also be called stenosis. It is usually caused by a buildup of fat or calcium deposits called plaque. Over time, this plaque can build to a total blockage of the artery. This is also called atherosclerosis.

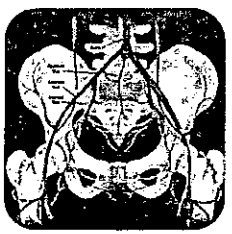


Healthy Iliac Artery | **Narrowed Iliac Artery**

When a leg doesn't receive enough blood flow because of a blockage in an artery, it can cause pain in the lower leg when walking. In severe cases, low blood flow can cause tissue loss.

Iliac Arteries

You have two iliac arteries, one located at the top of each leg. The iliac arteries start at the base of the aorta, just behind the navel (belly button). The iliac arteries branch into smaller arteries that supply blood to the legs and feet.



Iliac artery disease treatment options

There are four different treatment options for iliac artery disease. All four treatment options focus on increasing blood flow to the legs. The type of treatment your doctor recommends depends on your symptoms.

1. Medical therapy
For patients with mild to medium symptoms, doctors often choose medical therapy. This can include drugs, exercise, and regular checkups. Doctors also say to stop smoking. The doctor may prescribe drugs to decrease clotting, expand the arteries, lower blood pressure, and reduce cholesterol. Regular checkups can help determine if more treatment is needed.

2. Angioplasty
A procedure, angioplasty, can also treat vessel narrowing. A thin tube known as a guide catheter is inserted into the artery. A small balloon located on the tip of a catheter is moved to the site of the narrowing and inflated to reduce the blockage. The balloon is deflated and removed after the angioplasty is done. Angioplasty is less invasive than surgery, and the patient remains awake while the doctor performs the procedure.

3. Iliac artery stenting
During this procedure, a small balloon is inflated in the artery. The balloon has a small mesh tube called a stent wrapped around it. It expands the stent in the artery which keeps the artery open and helps prevent further narrowing.

4. Surgery
For patients with severe narrowing with blocked blood flow to the legs, surgery may be needed. There are two types of surgery to treat iliac artery disease. During an iliac artery endarterectomy, the doctor makes an incision in the pelvis. This exposes the iliac artery and the plaque inside the artery is removed. Patients who have this type of surgery are usually in the hospital for about a week. In an iliac artery bypass, a healthy vein is removed from another part of your body. This vein is used to make a new path around the narrowed or blocked iliac artery. Patients are also in the hospital for about a week after this surgery.

Risks

You should not have a stent placed in your iliac artery if you have any of the following conditions:

- You are unable to take medicines that make your blood take longer to clot (anticoagulants).
- You are unable to take medicines that make your blood cells slippery and make it more difficult for your blood to clot (antiplatelets).
- You are allergic to stainless steel, chromium or nickel. These are the metals used to make the Express® LD Iliac Premounted Stent System.
- You have poor kidney function.

Note: It is very common for your doctor to prescribe specific medications before, during and after your stent placement. Common drugs that may be prescribed by your doctor include anticoagulants and antiplatelets. These medications are intended to help decrease the risk of forming a blood clot in your artery. Please check with your doctor to find the right medication for you.

Risks *continued*

The placement of stents in blood vessels is done to treat blockages and to try to prevent re-narrowing.

As with any stent procedure, there is chance that complications may occur, including, but not limited to, the following:

- Air bubble(s) in your artery
- Allergic reactions
- Bleeding
- Blood clot(s)
- Bruising at you groin area
- Death
- Heart attack
- Infection
- Injury or damage to your artery or wall of the artery. This could require emergency surgery
- Leakage of blood where the catheter was inserted
- Movement of the stent from where it was original placed
- Restenosis or re-narrowing of the artery around or within the stent
- In the event of complications, surgical removal of the stent may be required

Your doctor and the medical staff will monitor you during and after the procedure for complications. If a complication does occur, your doctor will decide if you require treatment. He or she will determine what type of treatment you need.

Benefits

The benefits of undergoing iliac stent placement can be improved blood flow to the legs through the artery being treated. If you had symptoms before surgery, they might improve or go away.

Summary of clinical data

The safety and effectiveness of the Express LD Premounted Stent System was compared to the Palmaz® Stent in the International MELODIE study. It included 151 patients. The study results showed that patients who received an Express LD Stent had similar blood vessel narrowing at six months compared to patients who received a Palmaz Stent. The occurrence of major adverse events was 6.3% at 6 months and 10.2% at 2 years for the Express LD Premounted Stent System. Major adverse events include death, repeat angioplasty and distal embolization.

The long term outcome (beyond 24 months) for this permanent implant is unknown.

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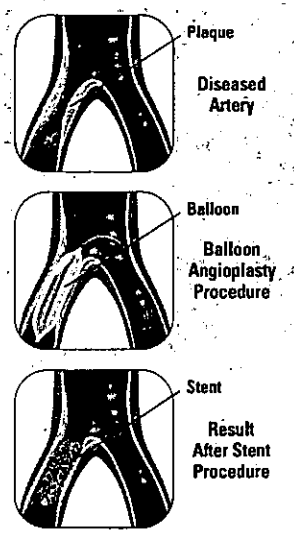
Before your procedure

Below is a typical checklist. Your doctor may ask you to go through this before your procedure.

- ☐ Tell your doctor about any medications you are taking.
- ☐ Take all your medications with you.
- ☐ Let your doctor know about any allergies you have. It is important he or she knows about allergies to contrast dye, iodine, cobalt, chromium, nickel, titanium, stainless steel or plastics.
- ☐ Tell your doctor if you cannot take aspirin or blood thinning medicines. These medications are usually prescribed before and after your procedure.
- ☐ Do not eat or drink anything after midnight on the night before your procedure.
- ☐ Follow the instructions you receive from your doctor and nurses.
- ☐ Make sure you understand the possible risks and benefits of your iliac stent procedure.
- ☐ You could be given a sedative to relax you before starting your stent procedure. The sedative can make you sleepy.

During a typical iliac artery stenting procedure

1. A small puncture is made in your groin. A needle is used to gain access to the femoral artery. This wire is then fed through the femoral artery and moved up into the iliac artery. A catheter is then put in your body. The doctor moves it to the narrowed section of your iliac artery. All wire and catheter movement is done using x-rays for a guide.
2. The diseased artery first needs to be enlarged to make room for the stent. To do this, the doctor places a small, deflated balloon over the wire and through the catheter to the blocked area of the iliac artery. When the balloon is in the correct position, it is inflated. This pushes the plaque buildup aside and reopens the artery to restore blood flow.
3. The balloon is deflated and removed, and a small metal mesh tube called a stent is advanced into the same blocked area of the artery and expanded against the artery wall.
4. After the stent is implanted, the catheter and wire are removed and the puncture site in your groin is closed. The stent remains in place and is designed to help keep the artery open and prevent future narrowing of the iliac artery.



Images courtesy of Boston Scientific. Images are for illustration purposes only, and are not necessarily to scale.

After a typical iliac stenting procedure

- You may feel sleepy from the sedative given to you. This will wear off over the next few hours.
- You will be taken to a unit where nurses and doctors can monitor you.
- Your heart rate, blood pressure, brain function and the entry site in your groin will be checked frequently.
- You will be asked to drink a lot of liquids to flush the contrast dye out of your system. You will have to stay in bed for several hours. You will be asked to keep your leg straight so the entry site in your groin can heal well.
- You may need a short hospital stay.
- You should alert your doctor or nurse if you experience any of these symptoms
  - Severe dizziness, near blackout or fainting
  - Severe headache that doesn't go away
  - Sudden blurriness or blindness in one or both eyes
  - Sudden weakness or clumsiness in your hand
  - Sudden weakness or paralysis of the face, arm or leg
  - Unexplained slurring of speech or difficulty understanding what is said
  - Pain, bleeding or infection at the entry site in your groin
- You should avoid straining yourself or lifting items heavier than 5 pounds until your doctor lets you know that it is okay to do so.

Your stent implant card

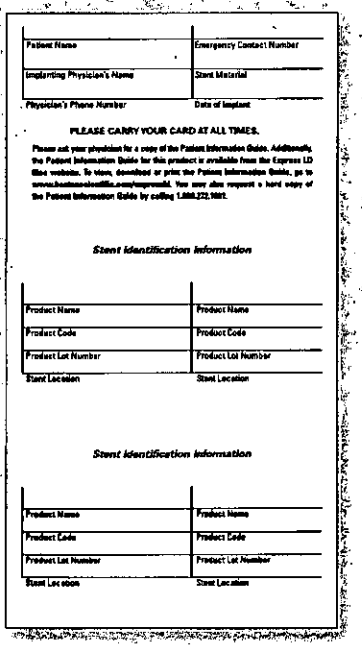
Your stent implant card shown at right tells doctors, dentists and nurses that you have a stent implanted in your iliac artery. This card also has:

- The doctor who put in your stent
- The doctor's phone number
- The date the stent was put in
- Where the stent was placed in your iliac artery
- The size of the stent
- The manufacturer's lot number for the stent

The card gives your doctors, dentists and nurses information that is needed if you have any special diagnostic tests such as:

- MRI

There are also phone numbers on the card that your doctors can call if they have any questions. You discharge nurse will fill in the card. If he or she does not, please call the doctor who placed the stent for this information.



Patient Name	Emergency Contact Number
Implanting Physician's Name	Stent Material
Physician's Phone Number	Date of Implant

PLEASE CARRY YOUR CARD AT ALL TIMES.

Please ask your physician for a copy of the Patient Information Guide. Additionally, the Patient Information Guide for this product is available from the Express LD Elite website. To view, download or print the Patient Information Guide, go to www.bostonscientific.com/expressld. You may also request a hard copy of the Patient Information Guide by calling 1.888.272.1881.

Stent Identification Information

Product Name	Product Name
Product Code	Product Code
Product Lot Number	Product Lot Number
Stent Location	Stent Location

Stent Identification Information

Product Name	Product Name
Product Code	Product Code
Product Lot Number	Product Lot Number
Stent Location	Stent Location

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Living with iliac artery disease

Treatment for iliac artery disease includes controlling things that cause the disease. You cannot control some risk factors. You cannot change your age, gender, ethnic background or family history. However, you can change many of the risk factors for this disease.

Your doctor may suggest the following healthy lifestyle changes:

- Lose excess weight
- Quit smoking
- Exercise regularly
- Control stress and anger
- Decrease fat in your diet
- Limit alcohol consumption

Reducing your risk factors can also have a positive impact on the long-term success of iliac artery disease treatment. Talk to your doctor today about how to increase your chances for a healthier outcome and a more rewarding life with iliac artery disease.

Glossary

Angioplasty
A minimally invasive treatment of the arteries that opens blocked arteries.

Anticoagulant and Antiplatelet
Medicines that slow down the clotting of blood.

Artery
A blood vessel that carries oxygen-rich blood away from the heart to the rest of the body.

Atherosclerosis
A disease in which the flow of blood is slowed down by plaque in the arteries.

Balloon Angioplasty
Inflating a balloon catheter in the blood vessel to open a blocked artery.

Balloon Catheter
A thin tube with a balloon attached to the tip that can be inflated to open blocked arteries.

Blood Vessel
Any of the veins and arteries that carry blood to and from the heart.

Catheter
A long, flexible tube that can be passed through the blood vessels.

Contrast
X-ray dye used in diagnostic tests.

Claudication
Pain that develops in the calf muscles of the legs. It can cause limping and an inability to walk long distances.

Femoral Artery
The blood vessels that supply blood to the legs.

Iliac Arteries
The blood vessels that supply blood to the legs.

Glossary *continued*

Iliac Artery Bypass
A surgical procedure used to create an alternate route for blood to flow to the legs around narrowed or blocked iliac arteries.

Iliac Artery Endarterectomy
A surgical procedure that removes plaque from the walls of the iliac arteries.

Minimally Invasive Procedure
A procedure that uses small instruments or devices to reduce the size of the insertion site and cause a smaller amount of trauma

MRI (Magnetic Resonance Imaging)
A method of using a magnetic field and radio waves to produce detailed images of the inside of the human body.

Occlusion
Blockage of blood flow in the artery.

Peripheral
Related to areas of the body outside the heart and brain.

Plaque
A buildup of cholesterol, fat calcium and collagen in a vessel.

Restenosis
Re-narrowing of the artery after treatment.

Sedative
A type of medication that makes you relaxed and sleepy. Also called sedation.

Stenosis
A narrowing of the artery.

Stent
An expandable metal tube that supports the blood vessel wall and maintains blood flow through the opened vessel.

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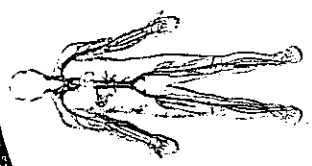
Express® LD Iliac
Premounted Stent System



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Magnetic Resonance Conditional

Non-clinical testing has demonstrated the Express LD Stent in single and overlapped conditions is MR Conditional. It can be scanned safely, immediately after placement of this implant, under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Spatial gradient field of 700 Gauss/cm or less
- Normal operating mode of the MR system and use of whole body transmit coils only
- Maximum whole-body-averaged specific absorption rate (WBA-SAR) of 2 Watts/kilogram, (W/kg), for 15 minutes of scanning for patient landmarks above the umbilicus (patient navel)
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus

It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

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Patient Name	Emergency Contact Number
Implanting Physician's Name	Stent Material
Physician's Phone Number	Date of Implant

PLEASE CARRY YOUR CARD AT ALL TIMES.

Please ask your physician for a copy of the Patient Information Guide. Additionally, the Patient Information Guide for this product is available from the Express LD Iliac website. To view, download or print the Patient Information Guide, go to www.bostonscientific.com/expressld. You may also request a hard copy of the Patient Information Guide by calling 1.888.272.1001.

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Stent Identification Information

Product Name	Product Name
Product Code	Product Code
Product Lot Number	Product Lot Number
Stent Location	Stent Location

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Stent Identification Information

Product Name	Product Name
Product Code	Product Code
Product Lot Number	Product Lot Number
Stent Location	Stent Location

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Express® LD Iliac
OVER – THE – WIRE
Premounted Stent System

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Please read instructions carefully prior to use!

WARNING:
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE NAME:
Express LD Iliac Premounted Stent System.

DEVICE DESCRIPTION:
The Express LD Iliac Premounted Stent System consists of: 316L surgical grade stainless steel balloon expandable stent. The stent is premounted on a Stent Delivery System (SDS) equipped with a non compliant balloon. The SDS has two radiopaque balloon markers embedded in the shaft to aid in the placement of the stent. The SDS is compatible with .035 in. (0.89 mm) guidewires. The SDS balloon has a maximum inflation pressure of 12 atm (1216 kPa) that can be used for initial stent placement and post stent dilatation. The premounted stent system is available in a variety of stent lengths with premounted stent system balloons that expand them from 6 mm to 10 mm in diameter. The premounted stent system balloon catheter is also offered in two shaft lengths. Table 1 summarizes individual product descriptions and nominal specifications.

Note: The diameter of the stent may be increased post-placement by expanding with a larger diameter balloon.

INTENDED USE/INDICATIONS FOR USE:
The Express LD Iliac Premounted Stent System is indicated for the treatment of atherosclerotic lesions found in iliac arteries up to 100 mm in length, with a reference diameter of 6 mm to 10 mm.

CONTRAINDICATIONS:
Generally, contraindications for Percutaneous Transluminal Angioplasty (PTA) are also contraindications for stent placement. Contraindications associated with the use of the Express LD Iliac Premounted Stent System include:

- Patients who exhibit persistent acute intraluminal thrombus at the treatment site, following thrombolytic therapy.
- Patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy
- Persons with known allergies to stainless steel or its components (for example nickel)
- A lesion that is within or adjacent to the proximal or distal segments of an aneurysm
- Patients who experience the complication of arterial perforation or a fusiform or sacciform aneurysm during the procedure, precluding possible stent implantation.
- Patients with excessive vessel tortuosity
- Patients with perforated vessels evidenced by extravasation of contrast media

WARNINGS:
Do not exceed the maximum rated burst pressure. Exceeding this pressure increases the potential for balloon rupture and possible vessel damage.

As with any type of intravascular implant, infection, secondary to contamination of the stent, may lead to thrombosis, pseudoaneurysm or rupture into a neighboring organ or into the retroperitoneum. The stent may cause thrombus or distal emboli to migrate from the site of the implant down the arterial lumen.

Care should be taken during stent deployment to avoid stent placement beyond the iliac ostium into the aorta as this may result in thrombus formation.

Do not exceed the maximum expanded stent diameter as per **Table 1**.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just distal to the stenosis. Overstretching of the artery may result in rupture and life threatening bleeding.

Use only diluted contrast medium for balloon inflation (typically a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium in the balloon.

Persons with allergic reactions to stainless steel or its components (for example nickel) may suffer an allergic response.

Do not expose the premounted stent system to organic solvents (i.e. alcohol).

This product contains no detectable latex.

The long-term outcome (beyond twenty four months) for this permanent implant is unknown at present.

Stent placement should only be performed at hospitals where emergency peripheral artery bypass graft can be readily performed.

PRECAUTIONS:
The device is intended for use by physicians who have been trained in interventional techniques such as percutaneous transluminal angioplasty (PTA) and placement of intravascular stents.

The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect, it should not be used.

Caution should be taken with patients with poor renal function who, in the physician's opinion, may be at risk for a contrast medium reaction.

Prep premounted stent system per instructions given in Operational Instructions. Significant amounts of air in the balloon may cause difficulty in deploying the stent and deflation of the balloon.

Do not attempt to pull a stent where deployment has been initiated back through a sheath or guide catheter, since dislodgment of the stent may result. If a stent that has not been fully deployed needs to be removed, the sheath or guide catheter and the premounted stent system should be removed as a unit.

The SDS is not designed for use with power injection systems. Inflation at a high rate can cause damage to the balloon. Use of a pressure monitoring device is recommended to prevent over pressurization.

Do not attempt to manually remove or adjust the stent on the SDS balloon.

The minimally acceptable sheath and guide catheter French size is printed on the package label. Do not attempt to pass the premounted stent system catheter through a smaller size sheath or guide catheter than indicated on the label.

When a premounted stent system or SDS balloon is in the body, it should be manipulated only under fluoroscopy. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.

Never advance the premounted stent system without the guidewire extending from the tip.

Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the stent. If the target lesion is not fully covered, use an additional stent as necessary to adequately treat the lesion.

It is recommended that when stenting multiple lesions, the distal lesions should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent when placing the distal stent and reduces the chances for disrupting the proximal stent.

Prior to stent expansion, utilize fluoroscopy to verify the stent has not been damaged or dislodged during positioning. Expansion of the stent should not be undertaken if the stent is not appropriately positioned in the vessel. If the position of the stent is not optimal, it should not be expanded.

To assure full expansion, inflate the premounted stent system to at least the opening pressure as shown on the labeling and in Table 1. To assure nominal sizing of the stent, inflate the premounted stent system to nominal pressure as shown on the labeling and in Table 1.

Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures, or could result in thrombosis of the side branch.

More than one stent per lesion should only be used when clinically indicated for suboptimal results that compromise vessel integrity and threaten vessel closure, such as edge dissection ≥type B (i.e. bailout). The second implanted stent should also be an Express® LD Iliac Stent, or a stent of similar material composition, for component compatibility.

Do not attempt to reposition a partially deployed stent. Attempted repositioning may result in severe vessel damage. Incomplete deployment of the stent (i.e. stent not fully opened) may cause complications resulting in patient injury.

Recrossing a previously deployed stent with adjunct devices must be performed with extreme caution to ensure that the adjunct device does not get caught within previously placed stent struts.

In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.

In the event of complications such as infections, pseudoaneurysm, or fistulization, surgical removal of the stent may be required.

Use prior to the "Use By" date.

Table 1. Express® LD ILIAC Premounted Stent System Specifications

Product Code	Crimped Stent Length (mm)	Balloon Size		Catheter Usable Length (cm)	Stent Nominal Pressure (atm (kPa))	Max. Rated Burst Pressure (atm (kPa))	Max. Expanded Stent Diameter (mm)	Minimum Introducer Sheath size (Fr (I.D. in.))
		Dia. (mm)	Length (mm)					
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H74938046630750	27	6	30	75	8 (811)	12 (1216)	9	6F(.085)
H74938046640750	37	6	40	75	8 (811)	12 (1216)	9	6F(.085)
H74938046660750	57	6	60	75	8 (811)	12 (1216)	9	6F(.085)
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H74938046730750	27	7	30	75	8 (811)	12 (1216)	9	6F(.085)
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H74938046760750	57	7	60	75	8 (811)	12 (1216)	9	6F(.085)
H74938046820750	17	8	20	75	8 (811)	12 (1216)	9	6F(.085)
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H74938046960750	57	9	60	75	8 (811)	12 (1216)	11	7F(.099)
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H74938047120130	25	10	30	135	10 (1013)	12 (1216)	11	7F(.099)
H74938047140130	37	10	40	135	10 (1013)	12 (1216)	11	7F(.099)
H74938047160130	57	10	60	135	10 (1013)	12 (1216)	11	7F(.099)

MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

Non-clinical testing has demonstrated the Express LD stent in single and overlapped conditions is MR Conditional. It can be scanned safely, immediately after placement of this implant, under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Spatial gradient field of 700 Gauss/cm or less
- Normal operating mode of the MR system and use of whole body transmit coils only.
- Maximum whole-body-averaged specific absorption rate (WBA-SAR) of 2 Watts/kilogram, (W/kg), for 15 minutes of scanning for patient landmarks above the umbilicus (patient navel).
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus.

The Express LD stent should not migrate in this MRI environment. Non-clinical testing at field strengths other than 1.5 Tesla or 3 Tesla has not been performed to evaluate stent migration or heating.

3.0 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 128 MHz in a 3.0 Tesla Magnetom Trio, Siemens Medical Solutions MR system, software version Numaris/4, syngo MR A30. The testing was according to ASTM F2182 and the stents were in a location and orientation in the phantom that produced the worst case Radio Frequency (RF) heating. RF power was applied for 15 minutes and the conductivity of the phantom material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was 1.8 W/kg. The maximal in-vitro temperature rise was 4.0°C when the local SAR was scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower temperature rise. Fractured stents exhibited similar heating. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded the following maximal in vivo rises:

- For landmarks above the umbilicus the calculated temperature rise was 5.2°C with an uncertainty upper bound temperature of 6.6°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.
- For landmarks below the umbilicus the calculated temperature rise was 4.1°C with an uncertainty upper bound temperature of 5.2°C for a whole body average SAR value of 1.0 W/kg and a continuous scan time of 15 minutes.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

1.5 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 64 MHz in a 1.5 Tesla Intera Philips Medical Systems, software version Release 10.6.2.0, 2006-03-10 whole body coil MR scanner. The testing was performed according to ASTM F2182 and the stents were in a location and orientation in the phantom that produced the worst case RF heating. RF power was applied for 15 minutes and the conductivity of the phantom material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was 2.1 W/kg. The maximal in-vitro temperature rise was 2.2°C when the local SAR was scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower

temperature rise. Fractured stents exhibited similar heating. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded to the following maximal in vivo rises:

- For landmarks above the umbilicus, the calculated temperature rise was 3.2°C with an uncertainty upper bound temperature of 4.1°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.
- For landmarks below the umbilicus the calculated temperature rise was 3.2°C with an uncertainty upper bound temperature of 4.1°C for a whole body average SAR value of 1.0 W/kg and a continuous scan time of 15 minutes.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flood in the lumen of the stent and blood perfusion in the tissue outside the stent.

Image Artifact Information

The image artifact extends approximately 7 mm from the perimeter of the device diameter and 6 mm beyond each end of the length of the stent when scanned in nonclinical testing using a Spin Echo sequence. With a Gradient Echo sequence the image artifact extends 13 mm beyond the perimeter of the diameter and 12 mm beyond each end of the length with both sequences partially shielding the lumen in a 3.0 Tesla Intera (Achieva Upgrade), Philips Medical Solutions, software version Release 2.5.3.0 2007-09-28 MR system with a transmit/receive head coil.

It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

ADVERSE EVENTS:

Potential adverse events (In alphabetical order) that may be associated with the use of this device, but are not limited to, the following:

- Abscess
- Aneurysm
- Arrhythmias
- AV fistula
- Bleeding / Hemorrhage
- Death
- Drug reaction or allergic reaction (including to antiplatelet agent, contrast medium, stent materials, or other)
- Embolization of device, air, plaque, thrombus, tissue, or other
- Emergency surgery to correct vascular complications
- Extremity ischemia/amputation
- Hematoma
- Hypotension or Hypertension
- Myocardial infarction
- Pseudoaneurysm formation
- Renal Insufficiency or Renal Failure
- Restenosis of the stented artery
- Sepsis/Infection

- Stent migration
- Stent thrombosis
- Stroke, TIA, or other cerebrovascular accident
- Vessel injury, including perforation, trauma, rupture, and dissection
- Vessel occlusion

Clinical Studies

BSC MELODIE Clinical Trial Safety Data

A total of 152 subjects at 10 centers were treated in this prospective, single-arm study. One subject was de-registered and excluded from the analysis because a signed consent form was not in place prior to the study index procedure. Therefore, a total of 151 enrolled subjects were included in the analysis. **Table 2** presents the principal effectiveness and safety results for the MELODIE trial through completion of the study at 24 months post-index procedure. **Figure 1** displays the Kaplan-Meier curve of Freedom from Major Adverse Events through the end of the study. Thirteen patients (10.2%) had Major Adverse Events as adjudicated by an independent Clinical Events Committee: 13 patients with Target Lesion Revascularizations, no distal embolization, and no deaths were adjudicated as device or procedure related. The nine deaths that occurred during the study period were due to cardiovascular causes (3), cancer (5), and respiratory insufficiency (1).

Table 2. Principal Effectiveness and Safety Results
All Treated Subjects (N=151)

Effectiveness and Safety Measures	(N=151 subjects) (N=163 lesions) (N=159 limbs)	[95% CI]
Effectiveness Measures		
Lesion Based		
Angiographic Mean Percent Loss of Lumen Diameter at 6 Months	16.2±18.4 (112) (-18.5, 100.0)	[12.8, 19.6]
Angiographic Binary Restenosis at 6 Months	5.6% (7/124)	[2.3%, 11.3%]
Angiographic Percent Diameter Stenosis at 6 Months	24.3±16.0 (124) (-9.5, 100.0)	[21.5, 27.1]
CTA Target Lesion Patency at 12 Months	97.2% (103/106)	[92.0%, 99.4%]
CTA Target Lesion Patency at 24 Months	94.1% (95/101)	[87.5%, 97.8%]
Technical Success[1]	98.0% (147/150)	[94.3%, 99.6%]
Subject Based		
Procedural Success[2]	97.1% (136/140)	[92.8%, 99.2%]
Clinical Success[3]		
30 Days	88.2% (127/144)	[81.8%, 93.0%]
6 Months	83.1% (108/130)	[75.5%, 89.1%]
12 Months	82.5% (99/120)	[74.5%, 88.8%]
24 Months	78.8% (89/113)	[70.1%, 85.9%]
Limb Based		
Hemodynamic Success[4]		
In-Hospital	75.3% (116/154)	[67.7%, 81.9%]
30 Days	79.3% (119/150)	[72.0%, 85.5%]
6 Months	71.2% (94/132)	[62.7%, 78.8%]
12 Months	60.2% (71/118)	[50.7%, 69.1%]
24 Months	57.9% (66/114)	[48.3%, 67.1%]
Safety Measures		
Lesion Based		
Target Lesion Revascularization		
In-Hospital	0.6% (1/163)	[0.0%, 3.4%]
30 Days	0.6% (1/163)	[0.0%, 3.4%]
6 Months	6.5% (10/154)	[3.2%, 11.6%]
12 Months	9.0% (13/145)	[4.9%, 14.8%]
24 Months	10.3% (14/136)	[5.7%, 16.7%]
End of Study	10.3% (14/136)	[5.7%, 16.7%]
Subject Based		
In-Hospital Major Adverse Events (MAE)	0.7% (1/151)	[0.0%, 3.6%]
Device/Procedure Related Death	0.0% (0/151)	[0.0%, 2.4%]
TLR	0.7% (1/151)	[0.0%, 3.6%]
Distal Embolization	0.0% (0/151)	[0.0%, 2.4%]
Major Adverse Events (MAE) through 30 Days	0.7% (1/151)	[0.0%, 3.6%]
Device/Procedure Related Death	0.0% (0/151)	[0.0%, 2.4%]
TLR	0.7% (1/151)	[0.0%, 3.6%]
Distal Embolization	0.0% (0/151)	[0.0%, 2.4%]
Major Adverse Events (MAE) through 6 Months	6.3% (9/144)	[2.9%, 11.5%]
Device/Procedure Related Death	0.0% (0/144)	[0.0%, 2.5%]
TLR	6.3% (9/144)	[2.9%, 11.5%]
Distal Embolization	0.0% (0/144)	[0.0%, 2.5%]
Major Adverse Events (MAE) through 12 Months	8.9% (12/135)	[4.7%, 15.0%]
Device/Procedure Related Death	0.0% (0/135)	[0.0%, 2.7%]
TLR	8.9% (12/135)	[4.7%, 15.0%]

Distal Embolization	0.0% (0/135)	[0.0%, 2.7%]
Major Adverse Events (MAE) between 24 Months	10.2% (13/127)	[5.6%, 16.9%]
Device/Procedure Related Death	0.0% (0/127)	[0.0%, 2.9%]
TLR	10.2% (13/127)	[5.6%, 16.9%]
Distal Embolization	0.0% (0/127)	[0.0%, 2.9%]
Major Adverse Events (MAE) through End of Study	10.2% (13/127)	[5.6%, 16.9%]
Device/Procedure Related Death	0.0% (0/127)	[0.0%, 2.9%]
TLR	10.2% (13/127)	[5.6%, 16.9%]
Distal Embolization	0.0% (0/127)	[0.0%, 2.9%]
Non-MAE Death		
Through 210 days	1.4% (2/144)	[0.2%, 4.9%]
Through 365 days	2.2% (3/137)	[0.5%, 6.3%]
Through 730 days	5.3% (7/131)	[2.2%, 10.7%]
Through End of Study	6.9% (9/131)	[3.2%, 12.6%]

* All measurements taken after a confirmed TLR are excluded from this table.

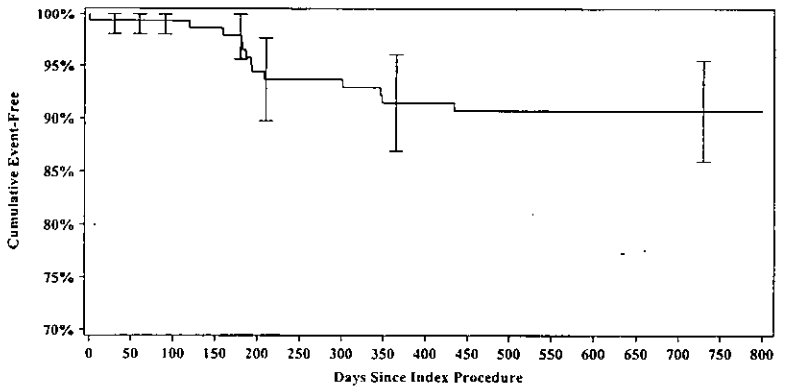
[1]Technical Success - successful delivery and deployment of the study stent to the target lesion with ≤ 30% residual stenosis as determined by angiography.

[2]Procedural Success - Technical Success without the occurrence of Major Adverse Events during the procedure and immediately post-procedure until discharge.

[3]Clinical Success - an improvement of the Fontaine classification by at least one class compared to the pre-procedure classification.

[4]Hemodynamic Success - improved ankle brachial index (ABI) by ≥ 0.1 above pre-procedure value and not deteriorated by > 0.15 from the maximum post-procedure value.

Figure 1. Freedom from Major Adverse Events (CEC Adjudicated) to End of Study
Event-Free Survival ± 1.96 SE, All Treated Subjects (N=151)



(N = 151 Subjects)	0	30	60	90	180	210	365	730	End of Study
Entered	151	150	149	145	144	141	129	123	71
Censored	0	1	4	1	1	6	3	51	71
At Risk	151	149.5	147	144.5	143.5	138	127.5	97.5	35.5
Events	1	0	0	0	2	6	3	1	0
Events/Month	30.0	0.0	0.0	0.0	0.7	6.0	0.6	0.1	0.0
Event Free	99.3%	99.3%	99.3%	99.3%	98.0%	93.7%	91.5%	90.7%	–
Std Error	0.7%	0.7%	0.7%	0.7%	1.2%	2.0%	2.3%	2.4%	--

Intervals are inclusive, e.g., interval 180 is defined as 91-180 days, inclusive.
Entered: # subjects eligible at the start of the interval.
Censored: # subjects censored during the interval.
At risk is # entered – half of # censored in the time interval.
Events: # subjects with events in the interval.
Survival rate estimates are from the Kaplan-Meier method, reported at each interval's end.
The standard error was calculated using Greenwood's formula.

BSC MELODIE Clinical Trial

Objective: The primary objective of the study was to obtain information on the safety and effectiveness of the Express LD Stent implantation in the treatment of stenosed or occlusive atherosclerotic disease (de novo or restenotic lesions) in the iliac arteries (common or external), and to demonstrate that the mean % loss of luminal diameter at six months post-stent implantation is non-inferior to an objective performance criterion (OPC) representative of the Palmaz® balloon-expandable stent.

Design: The MELODIE study was a prospective, single-arm, multicenter study conducted at 10 centers enrolling a total of 152 subjects. Subjects had chronic

symptomatic (Fontaine class IIa, IIb, or III) atherosclerotic disease in the iliac arteries with baseline percent diameter stenosis ≥ 50% by visual estimate. The diseased segment was required to be ≤ 10 cm long and treatable with a maximum of two overlapping Express LD Stents. Subjects with uncorrected bleeding disorders, contraindications to anticoagulation or antiplatelet therapy, intraluminal thrombus of the proposed treated lesion(s) post thrombolytic therapy, or known allergy to stainless steel were excluded from the study.

Before the stenting procedure, subjects were administered anticoagulant and/or antiplatelet treatment according to the routine practice of the participating study center. During the procedure, the use of heparin was permitted according to routine practice at the participating study center. After the procedure, subjects were to receive Aspirin® (acetylsalicylic acid) 100 mg administered once daily during the entire 24-month follow-up phase of the study. If use of Aspirin® (acetylsalicylic acid) was contraindicated for a subject, Plavix® (clopidogrel) 75 mg once daily was administered until the end of the study. Subjects were also permitted to take additional anticoagulant/antiplatelet medications, if indicated.

Follow-up included office visits at 30 days, 6 months (primary endpoint), 12 and 24 months, for a total follow-up period of 24 months post-index procedure. Angiographic follow-up was performed at 6 months and computed tomography angiography (CTA) follow-up was done at 12 and 24 months.

Endpoints: The primary endpoint of this study was angiographic mean percent loss of luminal diameter at 6 months post-procedure based on angiographic core lab assessment.

Secondary and tertiary endpoints included:

- technical success of ≤ 30% residual stenosis immediately post-procedure with successful stent delivery and deployment
- procedural success of technical success without major adverse events during the procedure and immediately post-procedure, until hospital discharge
- hemodynamic success of improved ABI by ≥ 0.1 above pre-procedure value and not deteriorated by >0.15 from the maximum post-procedure value at discharge, 30 days, 6 months, 12 months, and 24 months.
- clinical success of an improvement of the Fontaine classification by at least one class compared to the pre-procedure classification at 30 days, 6 months, 12 months, and 24 months.
- angiographic binary restenosis as stenosis of the target lesion > 50% of the reference vessel diameter at the time of assessment at 6 months.
- angiographic percent diameter stenosis post-procedure at 6 months.
- target lesion revascularization (TLR) at discharge, 30 days, 6 months, 12 months, and 24 months.
- major adverse events (MAEs) defined as device- and/or procedure-related death; target vessel revascularization; distal embolization related to the device requiring

hospitalization and/or subsequent intervention at discharge, 30 days, 6 months, 12 months, and 24 months.

- computer tomography angiography (CTA) target lesion patency post-procedure defined as the proportion of treated lesions with percentage diameter stenosis of the target lesion ≥ 50% of the reference vessel diameter at the time of assessment at 12 and 24 months.

The primary endpoint is met if the angiographic mean percent loss of luminal diameter for the Express LD Stent is statistically significantly lower than the objective performance criterion (OPC) representative of the Palmaz® balloon-expandable stent of 15% plus a non-inferiority margin of 5% (20.0%). *("Stenting of the Iliac arteries with the Palmaz® stent: Experience from a multicenter trial", Palmaz J et al., Cardiovascular Intervention Radiology 1992; 15: 291-297).*

Demographics: Baseline characteristics of the MELODIE clinical trial showed 74.8% were males. The average age was 60.1 (range 43 to 84 years), 12.6% had medically treated diabetes, 54.4% had a history of hyperlipidemia, 60.3% had hypertension, and 87.4% were current or previous smokers. Baseline lesion characteristics included mean reference vessel diameter (RVD) of 7.9 mm, mean minimum lumen diameter (MLD) of 3.3 mm, mean percent diameter stenosis (%DS) of 62.9%, and mean lesion length of 32.0 mm.

Table 3. Baseline Demographic Characteristics
All Treated Subjects (N=151)

Characteristic	(N =151 subjects)	[95% CI]
Demographics		
Male	74.8% (113/151)	[67.1%, 81.5%]
Female	25.2% (38/151)	[18.5%, 32.9%]
Age (yr)	60.1±8.4 (151) (43.0, 84.5)	[58.8, 61.5]
Risk factors		
Known Smoking, Ever	87.4% (132/151)	[81.0%, 92.3%]
Current	62.1% (82/132)	[53.3%, 70.4%]
Previous	37.9% (50/132)	[29.6%, 46.7%]
Known Medically Treated Diabetes	12.6% (19/151)	[7.7%, 19.0%]
Insulin Requiring	6.0% (9/151)	[2.8%, 11.0%]
Non-insulin Requiring	6.6% (10/151)	[3.2%, 11.8%]
Hypertension	60.3% (91/151)	[52.0%, 68.1%]
Hyperlipidemia	54.4% (80/147)	[46.0%, 62.6%]
Comorbidities		
History of Myocardial Infarction	22.0% (33/150)	[15.7%, 29.5%]
Angina Pectoris	14.7% (22/150)	[9.4%, 21.4%]
Stroke or Transient Ischemic Attack	7.3% (11/151)	[3.7%, 12.7%]
Renal Disease	1.3% (2/151)	[0.2%, 4.7%]
Chronic Obstructive Pulmonary Disease	8.7% (13/150)	[4.7%, 14.4%]
Previous treatment of atherosclerotic lesions in the iliac artery	10.7% (16/149)	[6.3%, 16.9%]
Previous vascular surgical intervention in legs	13.9% (21/151)	[8.8%, 20.5%]
Other Disease	28.5% (43/151)	[21.4%, 36.4%]
Platelet count ($x10^3$)	234.0±59.4 (143) (115.0, 420.0)	[224.3, 243.8]

Characteristic	(N =151 subjects)	[95% CI]
Claudication		
>1000 meters	1.3% (2/150)	[0.2%, 4.7%]
200 – 1000 meters	15.3% (23/150)	[10.0%, 22.1%]
< 200 meters	83.3% (125/150)	[76.4%, 88.9%]
Tissue Loss		
Right leg	0.0% (0/145)	[0.0%, 2.5%]
Left leg	0.0% (0/145)	[0.0%, 2.5%]

Table 4. Baseline Lesion Characteristics Determined by QVA
All Target Lesions (N=163) in All Treated Subjects (N=151)

Characteristic	(N = 163 lesions)	[95% CI]
Target Lesion Location		
Right Common Iliac Artery	22.1% (36/163)	[16.0%, 29.2%]
Right Common Iliac Artery Extending Into External	3.1% (5/163)	[1.0%, 7.0%]
Right External Iliac Artery	19.0% (31/163)	[13.3%, 25.9%]
Left Common Iliac Artery	19.0% (31/163)	[13.3%, 25.9%]
Left Common Iliac Artery Extending Into External	3.7% (6/163)	[1.4%, 7.8%]
Left External Iliac Artery	33.1% (54/163)	[26.0%, 40.9%]
Minimum Lumen Diameter (MLD, mm)	3.3±1.4 (99) (0.0, 8.2)	[3.0, 3.5]
Reference Vessel Diameter (RVD, mm)	7.9±1.6 (99) (5.0, 13.3)	[7.5, 8.2]
Mean Lumen Diameter (mm)	6.9±1.4 (99) (4.0, 11.9)	[6.7, 7.2]
Percent Diameter Stenosis (%DS)	62.9±19.3 (116) (30.2, 100.0)	[59.4, 66.4]
Target Lesion Length (mm)	32.0±21.7 (99) (3.9, 99.1)	[27.7, 36.3]

Methods: Clinical follow-up was conducted in-hospital, and at 30 days, 6 months, 12 and 24 months post-procedure. Follow-up angiography at 6 months was performed in 81.3% of the subjects. Follow-up CT angiography was performed in 83.1% of the subjects at 12 months, and in 83.8% of the subjects at 24 months. Angiographic and CTA data were assessed by quantitative analysis by a core laboratory. An independent Clinical Events Committee adjudicated Major Adverse Events.

Results: All subjects enrolled in the MELODIE trial received an Express LD stent. Procedural success was achieved in 97.1% of subjects, with technical success achieved in 98.0% of lesions. The four procedural failures were due to the residual percent diameter stenosis ≥ 30% (technical failures) in three subjects and the occurrence of one major adverse event before discharge. The three technical failures were due to residual percent diameter stenosis between 31.2% and 33.1% measured by QVA.

The mean percent luminal diameter loss at six months was 16.2%±18.4% for the Express LD stent. This result was statistically significantly lower (P=0.0061) than the OPC plus delta (15% + 5% = 20%) with an upper 95% confidence bound of 18.7%, demonstrating non-inferiority compared to the Palmaz stent for the treatment of atherosclerotic lesions in the iliac artery.

Table 5. Primary Endpoint: Angiographic Mean % Loss of Luminal Diameter All Treated Lesions (N=163) in All Treated Subjects (N=151)

	(N = 112 paired lesions)	Literature OPC	Delta	p-value
Angiographic Mean % Loss of Luminal Diameter	16.21±18.42	15.0±16.0	5.0	0.0061

* All measurements taken after a confirmed TLR are excluded from this table.

Table 6. Principal Effectiveness All Treated Subjects (N=151)

Effectiveness Measure	(N=151 subjects) (N=163 lesions) (N=159 limbs)	[95% CI]
Lesion Based		
Angiographic Mean Percent Loss of Lumen Diameter at 6 Months	16.2±18.4 (112) (-18.5, 100.0)	[12.8, 19.6]
Angiographic Binary Restenosis at 6 Months	5.6% (7/124)	[2.3%, 11.3%]
Angiographic Percent Diameter Stenosis at 6 Months	24.3±16.0 (124) (-9.5, 100.0)	[21.5, 27.1]
CTA Target Lesion Patency at 12 Months	97.2% (103/106)	[92.0%, 99.4%]
CTA Target Lesion Patency at 24 Months	94.1% (95/101)	[87.5%, 97.8%]
Technical Success	98.0% (147/150)	[94.3%, 99.6%]
Subject Based		
Procedural Success	97.1% (136/140)	[92.8%, 99.2%]
Clinical Success		
30 Days	88.2% (127/144)	[81.8%, 93.0%]
6 Months	83.1% (108/130)	[75.5%, 89.1%]
12 Months	82.5% (99/120)	[74.5%, 88.8%]
24 Months	78.8% (89/113)	[70.1%, 85.9%]
Limb Based		
Hemodynamic Success		
In-Hospital	75.3% (116/154)	[67.7%, 81.9%]
30 Days	79.3% (119/150)	[72.0%, 85.5%]
6 Months	71.2% (94/132)	[62.7%, 78.8%]
12 Months	60.2% (71/118)	[50.7%, 69.1%]
24 Months	57.9% (66/114)	[48.3%, 67.1%]

Table 7. Summary of Secondary and Tertiary Endpoints All Treated Subjects (N=151)

Effectiveness and Safety Measures	(N=151 subjects) (N=163 lesions) (N=159 limbs)	[95% CI]
Effectiveness Measures		
Lesion Based		
Angiographic Binary Restenosis at 6 Months	5.6% (7/124)	[2.3%, 11.3%]
Angiographic Percent Diameter Stenosis at 6 Months	24.3±16.0 (124) (-9.5, 100.0)	[21.5, 27.1]
CTA Target Lesion Patency at 12 Months	97.2% (103/106)	[92.0%, 99.4%]
CTA Target Lesion Patency at 24 Months	94.1% (95/101)	[87.5%, 97.8%]
Technical Success	98.0% (147/150)	[94.3%, 99.6%]
Subject Based		
Procedural Success	97.1% (136/140)	[92.8%, 99.2%]
Clinical Success		
30 Days	88.2% (127/144)	[81.8%, 93.0%]
6 Months	83.1% (108/130)	[75.5%, 89.1%]
12 Months	82.5% (99/120)	[74.5%, 88.8%]
24 Months	78.8% (89/113)	[70.1%, 85.9%]
Limb Based		
Hemodynamic Success		
In-Hospital	75.3% (116/154)	[67.7%, 81.9%]
30 Days	79.3% (119/150)	[72.0%, 85.5%]
6 Months	71.2% (94/132)	[62.7%, 78.8%]
12 Months	60.2% (71/118)	[50.7%, 69.1%]
24 Months	57.9% (66/114)	[48.3%, 67.1%]
Safety Measures		
Lesion Based		
Target Lesion Revascularization		
In-Hospital	0.6% (1/163)	[0.0%, 3.4%]
30 Days	0.6% (1/163)	[0.0%, 3.4%]
6 Months	6.5% (10/154)	[3.2%, 11.6%]
12 Months	9.0% (13/145)	[4.9%, 14.8%]
24 Months	10.3% (14/136)	[5.7%, 16.7%]
Subject Based		
Major Adverse Events (MAE)		
In-Hospital	0.7% (1/151)	[0.0%, 3.6%]
30 Days	0.7% (1/151)	[0.0%, 3.6%]
6 Months	6.3% (9/144)	[2.9%, 11.5%]
12 Months	8.9% (12/135)	[4.7%, 15.0%]
24 Months	10.2% (13/127)	[5.6%, 16.9%]

All measurements taken after a confirmed TLR are excluded from this table.

Retrospective Performance Goal

To assess further the safety and effectiveness of the Express LD Stent in the treatment of stenosed or occlusive atherosclerotic iliac artery disease, a composite safety and effectiveness performance goal was developed from contemporary literature, and retrospectively applied to the MELODIE data.

The endpoint for this retrospective performance goal is a composite of the following safety and effectiveness endpoints:

- procedure/device-related death to 30 days
- in-hospital MI
- TLR through 12 months (365 days)
- amputation of the target limb through 12 months (365 days)

Based on a review of the literature, the expected rate for this endpoint at 12 months was estimated to be 10%. Using a delta of 9%, the performance goal for this endpoint was 19%.

The observed rate of this endpoint in the MELODIE trial was 11.1% with a one-sided 95% upper confidence limit of 16.7% (see Table 8). This is lower than the performance goal of 19%, further supporting the safety and effectiveness of iliac stenting with the Express LD stent.

Table 8. Analysis of 12-month Composite Safety and Effectiveness Endpoint for the MELODIE study
All Treated Patients (N=151)

Endpoint	(N=151 Patients)	One-sided 95% upper CI to test the performance goal*
12-Month MAE	11.1% (15/135)	16.7%
Procedure/device-related death to 30 days	0.0% (0/135)	
In-hospital MI	0.7% (1/135)	
TLR to 12 months	8.9% (12/135)	
Amputation to 12 months	2.2% (3/135)	

* The hypotheses for testing the performance goal of 19% are: H_0: $\pi \geq 19\%$ and H_1: $\pi < 19\%$, where π is the rate of 12-month MAE for the MELODIE study. To conclude the Express LD stent is significantly less than the performance goal, the one-sided 95% upper confidence interval under H_0 from the MELODIE study must be less than 19%.

Overlapping Stent Analysis

An analysis was completed comparing outcomes in subjects with overlapping stents to those without. Twenty-seven subjects in the MELODIE study had overlapping stents placed. Table 9 shows the number of subjects that had overlapping stents by overlap configuration.

Table 9: Quantity of Overlapping Stent Configurations

Stent Size	27 mm	37 mm	57 mm
25 mm	0	1	0
27 mm	1	2	1
37 mm	--	8	7
57 mm	--	--	7

Table 10 displays outcomes in MELODIE subjects treated with overlapping stents compared to those without overlapping stents. In general, outcomes in patients treated with overlapping stents are similar to outcomes in patients not treated with overlapping stents. Technical, procedural and hemodynamic success endpoints were very similar between the two groups. There were no device or procedure related deaths and no instances of distal embolization in either group. Any conclusions drawn from Table 10

must be interpreted with caution as the MELODIE study was not designed or powered to compare outcomes in patients with and without overlapping stents. It is generally known that there is a trend for more MAEs, particularly TVR, in patients with overlapped stents and longer lesions in the peripheral arteries, just as is seen in the coronary arteries.

Table 10: Principal Effectiveness and Safety Results, Patients with overlapping stents versus patients with no overlapping stents

	Subjects with overlapping stents		Subjects with no overlapping stents	
Effectiveness and Safety Measures	**(N=27 subjects) (N=34 lesions) (N=32 limbs)**	**[95% CI]**	**(N=124 subjects) (N=129 lesions) (N=127 limbs)**	**[95% CI]**
Effectiveness Measures				
Lesion Based				
Angiographic Mean Percent Loss of Lumen Diameter at 6 Months	18.3±22.4 (26) (-18.5, 100.0)	[9.7, 26.9]	15.6±17.1 (86) (-18.3, 100.0)	[12.0, 19.2]
Angiographic Binary Restenosis at 6 Months	11.1% (3/27)	[2.4%, 29.2%]	4.1% (4/97)	[1.1%, 10.2%]
Angiographic Percent Diameter Stenosis at 6 Months	28.2±19.3 (27) (8.8, 100.0)	[20.9, 35.5]	23.2±14.8 (97) (-9.5, 100.0)	[20.2, 26.1]
CTA Target Lesion Patency at 12 Months	90.9% (20/22)	[70.8%, 98.9%]	98.8% (83/84)	[93.5%, 100.0%]
CTA Target Lesion Patency at 24 Months	90.5% (19/21)	[69.6%, 98.8%]	95.0% (76/80)	[87.7%, 98.6%]
Technical Success	96.9% (31/32)	[83.8%, 99.9%]	98.3% (116/118)	[94.0%, 99.8%]
Subject Based				
Procedural Success	96.2% (25/26)	[80.4%, 99.9%]	97.4% (111/114)	[92.5%, 99.5%]
Clinical Success				
30 Days	92.0% (23/25)	[74.0%, 99.0%]	87.4% (104/119)	[80.1%, 92.8%]
6 Months	91.3% (21/23)	[72.0%, 98.9%]	81.3% (87/107)	[72.6%, 88.2%]
12 Months	90.5% (19/21)	[69.6%, 98.8%]	80.8% (80/99)	[71.7%, 88.0%]
24 Months	95.0% (19/20)	[75.1%, 99.9%]	75.3% (70/93)	[65.2%, 83.6%]
Limb Based				
Hemodynamic Success				
In-Hospital	81.3% (26/32)	[63.6%, 92.8%]	73.8% (90/122)	[65.0%, 81.3%]
30 Days	80.6% (25/31)	[62.5%, 92.5%]	79.0% (94/119)	[70.6%, 85.9%]
6 Months	89.3% (25/28)	[71.8%, 97.7%]	66.3% (69/104)	[56.4%, 75.3%]
12 Months	73.9% (17/23)	[51.6%, 89.8%]	56.8% (54/95)	[46.3%, 67.0%]
24 Months	69.6% (16/23)	[47.1%, 86.8%]	54.9% (50/91)	[44.2%, 65.4%]
Safety Measures				
Lesion Based				
Target Lesion Revascularization				
In-Hospital	0.0% (0/34)	[0.0%, 10.3%]	0.8% (1/129)	[0.0%, 4.2%]
30 Days	0.0% (0/34)	[0.0%, 10.3%]	0.8% (1/129)	[0.0%, 4.2%]
6 Months	12.9% (4/31)	[3.6%, 29.8%]	4.9% (6/123)	[1.8%, 10.3%]
12 Months	16.1% (5/31)	[5.5%, 33.7%]	7.0% (8/114)	[3.1%, 13.4%]
24 Months	16.7% (5/30)	[5.6%, 34.7%]	8.5% (9/106)	[4.0%, 15.5%]
End of Study	16.7% (5/30)	[5.6%, 34.7%]	8.5% (9/106)	[4.0%, 15.5%]
Subject Based				
In-Hospital Major Adverse Events (MAE)	0.0% (0/27)	[0.0%, 12.8%]	0.8% (1/124)	[0.0%, 4.4%]
Device/Procedure Related Death	0.0% (0/27)	[0.0%, 12.8%]	0.0% (0/124)	[0.0%, 2.9%]
TLR	0.0% (0/27)	[0.0%, 12.8%]	0.8% (1/124)	[0.0%, 4.4%]
Distal Embolization	0.0% (0/27)	[0.0%, 12.8%]	0.0% (0/124)	[0.0%, 2.9%]
Major Adverse Events (MAE) through 30 Days	0.0% (0/27)	[0.0%, 12.8%]	0.8% (1/124)	[0.0%, 4.4%]
Device/Procedure Related Death	0.0% (0/27)	[0.0%, 12.8%]	0.0% (0/124)	[0.0%, 2.9%]
TLR	0.0% (0/27)	[0.0%, 12.8%]	0.8% (1/124)	[0.0%, 4.4%]

Effectiveness and Safety Measures	Subjects with overlapping stents (N=27 subjects) (N=34 lesions) (N=32 limbs)	[95% CI]	Subjects with no overlapping stents (N=124 subjects) (N=129 lesions) (N=127 limbs)	[95% CI]
Distal Embolization	0.0% (0/27)	[0.0%, 12.8%]	0.0% (0/124)	[0.0%, 2.9%]
Major Adverse Events (MAE) through 6 Months	12.0% (3/25)	[2.5%, 31.2%]	5.0% (6/119)	[1.9%, 10.7%]
Device/Procedure Related Death	0.0% (0/25)	[0.0%, 13.7%]	0.0% (0/119)	[0.0%, 3.1%]
TLR	12.0% (3/25)	[2.5%, 31.2%]	5.0% (6/119)	[1.9%, 10.7%]
Distal Embolization	0.0% (0/25)	[0.0%, 13.7%]	0.0% (0/119)	[0.0%, 3.1%]
Major Adverse Events (MAE) through 12 Months	16.0% (4/25)	[4.5%, 36.1%]	7.3% (8/110)	[3.2%, 13.8%]
Device/Procedure Related Death	0.0% (0/25)	[0.0%, 13.7%]	0.0% (0/110)	[0.0%, 3.3%]
TLR	16.0% (4/25)	[4.5%, 36.1%]	7.3% (8/110)	[3.2%, 13.8%]
Distal Embolization	0.0% (0/25)	[0.0%, 13.7%]	0.0% (0/110)	[0.0%, 3.3%]
Major Adverse Events (MAE) between 24 Months	16.7% (4/24)	[4.7%, 37.4%]	8.7% (9/103)	[4.1%, 15.9%]
Device/Procedure Related Death	0.0% (0/24)	[0.0%, 14.2%]	0.0% (0/103)	[0.0%, 3.5%]
TLR	16.7% (4/24)	[4.7%, 37.4%]	8.7% (9/103)	[4.1%, 15.9%]
Distal Embolization	0.0% (0/24)	[0.0%, 14.2%]	0.0% (0/103)	[0.0%, 3.5%]
Major Adverse Events (MAE) through End of Study	16.7% (4/24)	[4.7%, 37.4%]	8.7% (9/103)	[4.1%, 15.9%]
Device/Procedure Related Death	0.0% (0/24)	[0.0%, 14.2%]	0.0% (0/103)	[0.0%, 3.5%]
TLR	16.7% (4/24)	[4.7%, 37.4%]	8.7% (9/103)	[4.1%, 15.9%]
Distal Embolization	0.0% (0/24)	[0.0%, 14.2%]	0.0% (0/103)	[0.0%, 3.5%]
Non-MAE Death				
Through 210 days	0.0% (0/25)	[0.0%, 13.7%]	1.7% (2/119)	[0.2%, 5.9%]
Through 365 days	0.0% (0/25)	[0.0%, 13.7%]	2.7% (3/112)	[0.6%, 7.6%]
Through 730 days	4.2% (1/24)	[0.1%, 21.1%]	5.6% (6/107)	[2.1%, 11.8%]
Through End of Study	4.2% (1/24)	[0.1%, 21.1%]	7.5% (8/107)	[3.3%, 14.2%]

* All measurements taken after a confirmed TLR are excluded from this table.

Conclusion: Overall, the MELODIE trial demonstrated the Express LD stent to be safe and effective in the treatment of stenosed or occlusive atherosclerotic iliac artery disease.

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HOW SUPPLIED:
Store in a cool, dry dark place.

Do not use if package is opened or damaged.

Do not store catheters where they are directly exposed to organic solvents or ionizing radiation. Excessive aging may cause the polymers used in these products to deteriorate. Rotate inventory so that the catheters and other dated products are used prior to the "Use By" date shown on the label.

Non-pyrogenic.

Contents:
- One (1) Express LD Iliac Premounted Stent System
- One (1) Electronic DFU Reference Card

OPERATIONAL INSTRUCTIONS:
Recommended Materials:
- Micropuncture™ kit
- .035 in. (0.89 mm) Guidewire of appropriate length
- Introducer/Guide sheaths of appropriate size and length, and equipped with a hemostatic valve
- Luer-lock Syringe [10 cc or greater for prepping the premounted stent system]
- 3 Way Stopcock
- Inflation device [20 cc or greater]

STENT PLACEMENT PROCEDURE:
Patient Preparation

The percutaneous placement of the stent in a stenotic or obstructed artery should be done in an angiography/ fluoroscopy procedure room. Patient preparation and sterile precautions should be the same as for any PTA procedure. Angiography/fluoroscopy should be performed to map out the extent of the lesion(s) and the collateral flow. Access vessels must be sufficiently patent, to proceed with further intervention. Multiple views are necessary for appropriate vessel sizing, and angiographic magnification is suggested.

Select Proper Premounted Stent System

1. Estimate the distance between the lesion and the entry site to select the proper premounted stent system length (refer to Table 1).
2. Measure the diameter of the reference vessel to determine the appropriate diameter stent and delivery balloon (refer to Table 1).

Note: To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just distal to the stenosis.

3. Measure the length of the target lesion to determine the length of the stent required. Size the stent length to extend slightly proximal and distal to the lesion. The appropriate stent length should be selected based on covering the entire lesion with a single stent (refer to Table 1).

Prepare the Premounted Stent System

1. Do not use product after the "Use By" date indicated on the package.
2. Open the box and remove the sterile package. Carefully inspect the sterile package before opening. Do not use if the integrity of the sterile package has been compromised.
3. Open package and remove hoop with premounted stent system.
4. Remove the premounted stent system from the hoop. Remove the stent protector and product mandrel.
5. Verify the stent is positioned between the proximal and distal balloon markers.

Caution: Do not attempt to manually reposition the premounted stent in any way. Check for bends, kinks and other damage. Do not use if any defects are noted.

6. Flush the premounted stent system guidewire lumen with heparinized normal saline.
7. Prepare inflation device/syringe with diluted contrast medium. The standard inflation medium is a 50/50 mixture of contrast medium and normal saline. Do not use air or any gaseous substance as a balloon inflation medium.
8. Attach inflation device/syringe to stopcock. Attach to premounted stent system inflation port.

Note: A 10 cc luer-lock syringe is recommended for use for aspirating this device.

9. Open stopcock to premounted stent system. With the distal balloon tip pointing down and placed below the level of the inflation device/syringe, pull negative pressure for 20-30 seconds. Carefully release to neutral for contrast fill.
10. Close stopcock to the premounted stent system; purge inflation device/syringe of all air.
11. Repeat steps 9 and 10 until all air is expelled. If bubbles persist, do not use the premounted stent system.
12. If a syringe was used for preparation, attach a prepared inflation device to stopcock.

Note: A 20 cc Inflation device is recommended for use with this device.

13. Open stopcock between the premounted stent system and the inflation device.

Delivery Procedure

1. Insert the appropriate sheath or guide catheter for the selected premounted stent system and procedure. Reference Table 1 for the minimum acceptable size for this device.

Caution: Always use an appropriately sized sheath for the implant procedure. It is advisable to use a sheath or guide catheter that is long enough to cross the lesion. Use of a guide sheath or guide catheter minimizes the risk of dislodging the stent from the balloon during tracking.

2. Advance a .035 in. (0.89 mm) guidewire of appropriate length across target lesion.

Note: It is strongly recommended that the guidewire remain across the lesion until the procedure is complete to avoid having to regain access.

3. Pre-dilate the lesion as necessary with a balloon dilatation catheter of appropriate size using conventional techniques.
4. After the lesion has been properly pre-dilated, remove the dilatation catheter.
5. Backload the premounted stent system onto proximal portion of guidewire while maintaining guidewire position across target lesion.
6. Carefully advance the premounted stent system into the hemostasis valve of the sheath or Y-adapter attached to the guide catheter. Ensure sheath/guide stability before advancing the premounted stent system into the vessel.

Caution: If resistance is encountered to the premounted stent system prior to exiting the sheath or guide catheter, do not force passage. Resistance may indicate a problem and may result in damage or dislodgement of the stent if forced. Maintain guidewire placement across the lesion and remove the premounted stent system with sheath or guide catheter as a single unit.

7. Advance premounted stent system over the guidewire to target lesion under direct fluoroscopic visualization.

Caution: If strong resistance is met during advancement of the premounted stent system, discontinue movement and determine the cause of the resistance before proceeding. If the cause of resistance cannot be determined, withdraw both the premounted stent system and sheath or guide catheter as a single unit.

8. Utilize the proximal and distal radiopaque markers as well as the radiopaque stent as reference points to position the stent in the lesion. During positioning, verify that the stent is still centered within the marker bands and has not been dislodged. Do not deploy the stent unless it is properly centered on the balloon and properly positioned within the target lesion. If the position of the stent within the lesion is not optimal, it should be carefully repositioned or removed. Removal of a stent that has not been expanded: Do not attempt to pull a premounted stent system that has been partially expanded back into the sheath or guide catheter, as dislodgement of the stent from the balloon may occur. The premounted stent system should be withdrawn until the proximal end of the stent is

aligned with the distal tip of the sheath or guide catheter. The sheath or guide catheter and premounted stent system should be removed as one unit.

Deployment Procedure

1. To deploy the stent, use an inflation device to slowly inflate the premounted stent system to at least the opening pressure shown in Table 1. Higher pressure may be necessary to optimize apposition against the lesion. Balloon pressures must not exceed rated burst pressure (12 atm /1216 kPa).

Note: It is strongly recommended that the guidewire remain across the lesion until the procedure is complete to avoid having to regain access.

2. After deploying the stent, slowly deflate the balloon manually using the inflation device to ensure proper balloon rewrap.

Caution: Allow adequate time for the balloon to fully deflate prior to removal. Observe fluoroscopically that the balloon is fully deflated prior to removal.

3. Position the sheath or guide to a coaxial position with the balloon catheter.
4. Maintaining proper sheath or guide catheter support, very slowly withdraw the balloon. Observe under fluoroscopy to ensure that the balloon disengages from the stent.

Caution: If resistance is encountered upon attempted removal, do not force removal, use fluoroscopy and conventional techniques to determine and remedy the cause of resistance before proceeding.

5. Confirm stent position and deployment using angiographic techniques. For optimal results, the entire lesion should be covered by the stent. Fluoroscopic visualization should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal reference vessel diameter.
6. If re-sizing is necessary, re-advance the SDS catheter, or another balloon catheter of appropriate size, to the stented area using standard angioplasty techniques.
7. While observing under fluoroscopy, inflate the balloon to the desired pressure; do not exceed the rated burst pressure. Do not expand the stent beyond maximum stent diameter as shown in Table 1. Deflate the balloon and follow the instructions as outlined in "Deployment Procedure" steps 3 and 4.
8. Reconfirm stent position and angiographic result. Repeat inflations until the desired result is achieved.
9. While maintaining negative pressure in the balloon, remove the SDS from the body through the sheath or guide catheter.

Table 11. Typical Express® LD Iliac Premounted Stent System Compliance

Pressure (atm-kpa)	Balloon Diameter (mm)				
	6.0 mm	7.0 mm	8.0 mm	9.0 mm	10.0 mm
6 - 608	5.79	6.69	7.60	8.67	9.57
7 - 709	5.83	6.76	7.70	8.75	9.69
8.0 – 811*	5.89*	6.85*	7.83*	8.87*	9.80
9.0 - 912	5.97	6.93	7.92	8.93	9.88
10.0 - 1013*	6.02	6.99	7.99	9.00	9.97*
11 - 1115	6.08	7.04	8.05	9.05	10.03
12 – 1216**	6.11	7.08	8.10	9.10	10.08
*Nominal Pressure					
**Rated Burst Pressure. DO NOT EXCEED.					
User should confirm stent diameter angiographically during balloon inflation.					

WARRANTY:
Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Micropuncture is a registered trademark of Cook, Inc.

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Express® LD Biliary

OVER – THE – WIRE
Premounted Stent System

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING:
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE NAME:
Express LD Biliary Premounted Stent System.

DEVICE DESCRIPTION:
The Express LD Biliary Premounted Stent System consists of:

A 316L surgical grade stainless steel balloon expandable stent. The stent is premounted on an over the wire Stent Delivery System (SDS) equipped with a non compliant balloon. The SDS balloon catheter has two radiopaque markers embedded in the shaft to aid in the placement of the stent. The SDS is compatible with 0.035 in (0.89 mm) guidewires. The SDS balloon has a maximum inflation pressure of 12 atm (1216 kPa) that can be used for initial stent placement and post stent dilatation.

The Premounted Stent System is available in a variety of stent lengths with SDS balloons that expand them from 5 mm to 10 mm in diameter. The SDS balloon catheter is also offered in two shaft lengths. Table 1 summarizes individual product descriptions and nominal specifications.

Note: The diameter of the stent may be increased post-placement by expanding with a larger diameter balloon. Do not exceed the maximum expanded stent diameter.

INTENDED USE/INDICATIONS FOR USE:
The Express LD Biliary Premounted Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

CONTRAINDICATIONS:
Contraindications associated with the use of the Express LD Biliary Premounted Stent System as a transhepatic endoprosthesis include:
• Stenting of a perforated duct where leakage from the duct could be exacerbated by the prosthesis.
• Patients with bleeding disorders.
• Severe ascites.

WARNINGS:
• Use only diluted contrast medium for balloon inflation (typically a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium in the balloon.
• Prepare Premounted Stent System per instructions given. Significant amounts of air in the balloon may cause difficulty in deploying the stent and deflation of the balloon.
• Do not exceed the maximum rated burst pressure.
• Persons with allergic reactions to stainless steel may suffer an allergic response to the implant.
• Do not expose the Premounted Stent System to organic solvents (i.e. alcohol).
• To reduce the potential for patient injury, the inflated diameter of the balloon should approximate the diameter of the duct just proximal and distal to the stricture. Overstretching of the duct may result in patient injury.
• The Express LD Biliary Stent may cause image artifacts with MRI scans due to distortion of the magnetic field.
• Stenting across a bifurcation could compromise future diagnostic or therapeutic procedures.

PRECAUTIONS:
• The device is intended for use by physicians who have received appropriate training.
• The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect, it should not be used.
• Do not attempt to pull a stent that has not been expanded back through an introducer sheath, since dislodgment of the stent may result. If a stent that has not been expanded needs to be removed, the introducer sheath and the Premounted Stent System should be removed as a unit.
• When treating multiple strictures, the stricture distal to the puncture site should be initially stented, followed by stenting of the proximal stricture. Stenting in this order eliminates the need to cross the proximal stent to achieve placement of the distal stent, and reduces the chance for dislodging the proximal stent with the SDS balloon or Premounted Stent System or dislodging the stent from the SDS balloon.
• The Premounted Stent System is not designed for use with power injection systems. Inflation at a high rate can cause damage to the balloon. Use of a pressure monitoring device is recommended to prevent over pressurization.

• Do not attempt to manually remove or adjust the stent on the SDS balloon.
• The minimally acceptable introducer sheath French size is printed on the package label. Do not attempt to pass the pre-mounted stent system through a smaller size introducer sheath than indicated on the label.
• When catheters are in the body, they should be manipulated only under fluoroscopy. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.
• Never advance the Premounted Stent System without the guidewire extending from the tip.
• Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the stent. If the target stricture is not fully covered, use additional stents as necessary to adequately treat the stricture.
• To ensure expansion of the premounted stent, inflate the Premounted Stent System to at least the opening pressure as shown on the label. To assure nominal sizing of the stent, inflate the Premounted Stent System to nominal pressure as shown on the label.
• Prior to stent expansion, utilize high-resolution fluoroscopy to verify the stent has not been damaged or dislodged during positioning. Expansion of the stent should not be undertaken if the stent is not appropriately positioned in the duct. If the position of the stent is not optimal, it should not be expanded.
• Do not attempt to reposition a partially deployed stent. Attempted repositioning may result in patient injury. Incomplete deployment of the stent (i.e. stent not fully opened) may cause complications resulting in patient injury.
• Recrossing a previously deployed stent with adjunct devices must be performed with extreme caution.
• In the event of complications (such as infections), surgical removal of the stent may be required. Standard surgical procedure is appropriate.
• When multiple stents are required, if placement results in metal to metal contact, stent materials should be of similar composition.

Table 1. Express® LD Biliary Premounted Stent System Specifications

Product Code	Crimped Stent Length (mm)	Balloon Size		Catheter Usable Length (cm)	Stent Nominal Pressure [atm (kPa)]	Max. Rated Burst Pressure [atm (kPa)]	Max. Expanded Stent Diameter (mm)	Minimum Introducer Sheath size [Fr (I.D. in.)]
		Dia. (mm)	Length (mm)					
H7493804652075O	17	5	20	75	8 (811)	12 (1216)	9	6F(.085)
H7493804653075O	27	5	30	75	8 (811)	12 (1216)	9	6F(.085)
H7493804654075O	37	5	40	75	8 (811)	12 (1216)	9	6F(.085)
H7493804656075O	57	5	60	75	8 (811)	12 (1216)	9	6F(.085)
H7493804662075O	17	6	20	75	8 (811)	12 (1216)	9	6F(.085)
H7493804663075O	27	6	30	75	8 (811)	12 (1216)	9	6F(.085)
H7493804664075O	37	6	40	75	8 (811)	12 (1216)	9	6F(.085)
H7493804666075O	57	6	60	75	8 (811)	12 (1216)	9	6F(.085)
H7493804672075O	17	7	20	75	8 (811)	12 (1216)	9	6F(.085)
H7493804673075O	27	7	30	75	8 (811)	12 (1216)	9	6F(.085)
H7493804674075O	37	7	40	75	8 (811)	12 (1216)	9	6F(.085)
H7493804676075O	57	7	60	75	8 (811)	12 (1216)	9	6F(.085)
H7493804682075O	17	8	20	75	8 (811)	12 (1216)	9	6F(.085)
H7493804683075O	27	8	30	75	8 (811)	12 (1216)	9	6F(.085)
H7493804684075O	37	8	40	75	8 (811)	12 (1216)	9	6F(.085)
H7493804686075O	57	8	60	75	8 (811)	12 (1216)	9	7F(.099)
H7493804692075O	25	9	30	75	8 (811)	12 (1216)	11	7F(.099)
H7493804694075O	37	9	40	75	8 (811)	12 (1216)	11	7F(.099)
H7493804696075O	57	9	60	75	8 (811)	12 (1216)	11	7F(.099)
H7493804610207O	25	10	30	75	10 (1013)	12 (1216)	11	7F(.099)
H7493804610407O	37	10	40	75	10 (1013)	12 (1216)	11	7F(.099))
H7493804610607O	57	10	60	75	10 (1013)	12 (1216)	11	7F(.099)
H7493804752013O	17	5	20	135	8 (811)	12 (1216)	9	6F(.085)
H7493804753013O	27	5	30	135	8 (811)	12 (1216)	9	6F(.085)
H7493804754013O	37	5	40	135	8 (811)	12 (1216)	9	6F(.085)
H7493804756013O	57	5	60	135	8 (811)	12 (1216)	9	6F(.085)
H7493804762013O	17	6	20	135	8 (811)	12 (1216)	9	6F(.085)
H7493804763013O	27	6	30	135	8 (811)	12 (1216)	9	6F(.085)
H7493804764013O	37	6	40	135	8 (811)	12 (1216)	9	6F(.085)
H7493804766013O	57	6	60	135	8 (811)	12 (1216)	9	6F(.085)
H7493804772013O	17	7	20	135	8 (811)	12 (1216)	9	6F(.085)
H7493804773013O	27	7	30	135	8 (811)	12 (1216)	9	6F(.085)
H7493804774013O	37	7	40	135	8 (811)	12 (1216)	9	6F(.085)
H7493804776013O	57	7	60	135	8 (811)	12 (1216)	9	6F(.085)
H7493804782013O	17	8	20	135	8 (811)	12 (1216)	9	6F(.085)
H7493804783013O	27	8	30	135	8 (811)	12 (1216)	9	6F(.085)
H7493804784013O	37	8	40	135	8 (811)	12 (1216)	9	6F(.085)
H7493804786013O	57	8	60	135	8 (811)	12 (1216)	9	7F(.099)
H7493804792013O	25	9	30	135	8 (811)	12 (1216)	11	7F(.099)
H7493804794013O	37	9	40	135	8 (811)	12 (1216)	11	7F(.099)
H7493804796013O	57	9	60	135	8 (811)	12 (1216)	11	7F(.099)
H7493804712013O	25	10	30	135	10 (1013)	12 (1216)	11	7F(.099)
H7493804714013O	37	10	40	135	10 (1013)	12 (1216)	11	7F(.099)
H7493804716013O	57	10	60	135	10 (1013)	12 (1216)	11	7F(.099)

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MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

Non-clinical testing has demonstrated the Express LD stent in single and overlapped conditions is MR Conditional. It can be scanned safely, immediately after placement of this implant, under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Spatial gradient field of 700 Gauss/cm or less
- Normal operating mode of the MR system and use of whole body transmit coils only.
- Maximum whole-body-averaged specific absorption rate (WBA-SAR) of 2 Watts/kilogram, (W/kg), for 15 minutes of scanning for patient landmarks above the umbilicus (patient navel).
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus.

The Express LD stent should not migrate in this MRI environment. Non-clinical testing at field strengths other than 1.5 Tesla or 3 Tesla has not been performed to evaluate stent migration or heating.

3.0 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 128 MHz in a 3.0 Tesla Magnetom Trio, Siemens Medical Solutions MR system, software version Numaris/4, syngo MR A30. The testing was according to ASTM F2182 and the stents were in a location and orientation in the phantom that produced the worst case Radio Frequency (RF) heating. RF power was applied for 15 minutes and the conductivity of the phantom material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was 1.8 W/kg. The maximal in-vitro temperature rise was 4.0°C when the local SAR was scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower temperature rise. Fractured stents exhibited similar heating. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded the following maximal in vivo rises:

- For landmarks above the umbilicus the calculated temperature rise was 5.2°C with an uncertainty upper bound temperature of 6.6°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.
- For landmarks below the umbilicus the calculated temperature rise was 4.1°C with an uncertainty upper bound temperature of 5.2°C for a whole body average SAR value of 1.0 W/kg and a continuous scan time of 15 minutes.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

1.5 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 64 MHz in a 1.5 Tesla Intera Philips Medical Systems, software version Release 10.6.2.0, 2006-03-10 whole body coil MR scanner. The testing was performed according to ASTM F2182 and the stents were in a location and orientation in the phantom that produced the worst case RF heating. RF power was applied for 15 minutes and the conductivity of the phantom material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was 2.1 W/kg. The maximal in-vitro temperature rise was 2.2°C when the local SAR was scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower

temperature rise. Fractured stents exhibited similar heating. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded to the following maximal in vivo rises:

- For landmarks above the umbilicus, the calculated temperature rise was 3.2°C with an uncertainty upper bound temperature of 4.1°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.
- For landmarks below the umbilicus the calculated temperature rise was 3.2°C with an uncertainty upper bound temperature of 4.1°C for a whole body average SAR value of 1.0 W/kg and a continuous scan time of 15 minutes.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flood in the lumen of the stent and blood perfusion in the tissue outside the stent.

Image Artifact Information

The image artifact extends approximately 7 mm from the perimeter of the device diameter and 6 mm beyond each end of the length of the stent when scanned in nonclinical testing using a Spin Echo sequence. With a Gradient Echo sequence the image artifact extends 13 mm beyond the perimeter of the diameter and 12 mm beyond each end of the length with both sequences partially shielding the lumen in a 3.0 Tesla Intera (Achieva Upgrade), Philips Medical Solutions, software version Release 2.5.3.0 2007-09-28 MR system with a transmit/receive head coil.

It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

ADVERSE EVENTS:

Potential complications associated with biliary stenting may include, but are not limited to:

- Abscess
- Allergic reaction (to drug, contrast, device or other)
- Bile duct injury, perforation, tear, or dissection
- Bleeding
- Cholangitis
- Death
- Drug reaction
- Embolization including device, air, or tissues
- Entanglement of delivery system in deployed stent
- Hemobilia
- Hypotension/hypertension
- Liver abscess
- Need for urgent intervention or surgery
- Pancreatitis
- Parenchymal hemorrhage
- Peritonitis
- Recurrent stricture

- Sepsis/infection
- Sludge occlusion
- Stent fracture
- Stent migration
- Stent misplacement
- Tissue ischemia/necrosis
- Tissue/tumor ingrowth causing recurrent stenosis or obstruction

HOW SUPPLIED:

Store in a cool, dry dark place.

Do not use if package is opened or damaged.

Do not store catheters where they are directly exposed to organic solvents or ionizing radiation. Excessive aging may cause the polymers used in these products to deteriorate. Rotate inventory so that the catheters and other dated products are used prior to the "Use By" date shown on the label.

Non-pyrogenic.

Contents:

- One (1) Express LD Biliary Premounted Stent System
- One (1) Electronic DFU Reference Card

OPERATIONAL INSTRUCTIONS:

Recommended Materials:

- Micropuncture™ kit
- 0.035 in Guidewire of appropriate length
- Introducer sheath of appropriate size and length
- Syringe (10 cc or greater for prepping the premounted stent system)
- 3 Way Stopcock
- Inflation device (20 cc or greater)

STENT PLACEMENT PROCEDURE:

Patient Preparation

The percutaneous placement of the stent in the biliary tree should be done in a procedure room equipped with appropriate imaging equipment. Patient preparation and sterile precautions should be the same as for any percutaneous cholangiogram procedure. A cholangiogram should be performed to map out the extent of the stricture in the biliary tree.

Select Proper Premounted Stent System

1. Estimate the distance between the stricture and the entry site to select the proper Premounted Stent System length (Refer to Table 1).
2. Measure the diameter of the reference duct to determine the appropriate diameter stent and delivery balloon (Refer to Table 1).

Note: To reduce the potential for damage to the duct, the inflated diameter of the Premounted Stent System should approximate the diameter of the duct just proximal and distal to the stricture.

3. Measure the length of the stricture to determine the length of the stent required. Size the stent length to extend slightly proximal and distal to the stricture. The appropriate stent length should be selected based on covering the entire stricture with a single stent (Refer to Table 1).

Prepare the Premounted Stent System
1. Do not use product after the "Use By" date indicated on the package.
2. Open the box and remove the sterile package. Carefully inspect the sterile package before opening it. Do not use if the integrity of the sterile package has been compromised.
3. Open package and remove hoop with Premounted Stent System.
4. Remove the Premounted Stent System from the hoop.
5. Verify the stent is positioned between the proximal and distal balloon markers.

Caution: Do not attempt to manually reposition the premounted stent in any way. Check for bends, kinks and other damage. Do not use if any defects are noted.

6. Flush the Premounted Stent System guidewire lumen with normal saline.
7. Prepare inflation device/syringe with diluted contrast medium. The standard inflation medium is a 50/50 mixture of contrast medium and normal saline. Do not use air or any gaseous substance as a balloon inflation medium.
8. Attach inflation device/syringe to stopcock; Attach to premounted stent system inflation port.

Note: A 10 cc syringe is recommended for use for aspirating this device.

9. Open stopcock to Premounted Stent System. With the distal balloon tip pointing down and placed below the level of the inflation device/syringe, pull negative pressure for 20-30 seconds. Carefully release to neutral for contrast fill.
10. Close stopcock to the Premounted Stent System; purge inflation device/syringe of all air.
11. Repeat steps 9 and 10 until all air is expelled. If bubbles persist, do not use the Premounted Stent System.
12. If a syringe was used for preparation, attach a prepared inflation device to stopcock.

Note: A 20 cc Inflation device is recommended for use with this device.

13. Open stopcock between the Premounted Stent System and the inflation device.

Delivery Procedure
1. Insert the appropriate introducer sheath for the selected Premounted Stent System. Reference Table 1 for the minimum acceptable size for this device.

Caution: Always use an appropriately sized introducer sheath for the implant procedure to protect the puncture site. It is advisable to use an introducer sheath that is long enough to cross the stricture. Use of an introducer sheath minimizes the risk of dislodging the stent from the balloon during tracking.

2. Advance a 0.035 in (0.89 mm) guidewire of appropriate length across target stricture.
3. Pre-dilate the stricture as necessary with a balloon dilatation catheter using conventional techniques.
4. After the stricture has been properly pre-dilated, remove the dilatation catheter.
5. Backload the Premounted Stent System on to the proximal portion of the guidewire, while maintaining guidewire position across target stricture.
6. Carefully advance the Premounted Stent System into the introducer sheath. Ensure introducer sheath stability before advancing the Premounted Stent System into the duct.

Caution: If resistance is encountered to the Premounted Stent System prior to exiting the introducer sheath, do not force passage. Resistance may indicate a problem and may result in damage or dislodgement of the stent if forced. Maintain guidewire placement across the stricture and remove the Premounted Stent System with the introducer sheath as a single unit.

7. Advance Premounted Stent System over the guidewire to target stricture under direct fluoroscopic visualization.

Caution: If strong resistance is met during advancement of the Premounted Stent System, discontinue movement and determine the cause of the resistance before proceeding. If the cause of resistance cannot be determined, withdraw both the Premounted Stent System and introducer sheath as a single unit.

8. Utilize the proximal and distal radiopaque balloon markers as well as the radiopaque stent as reference points to position the stent in the stricture. During positioning, verify that the stent is still centered within the marker bands and has not been dislodged. Do not deploy the stent unless it is properly centered on the balloon and properly positioned within the target stricture. If the position of the stent within the stricture is not optimal, it should be carefully repositioned or removed.
Removal of a stent that has not been expanded: Do not attempt to pull a Premounted Stent System that has not been expanded back into the introducer sheath, as dislodgement of the stent from the balloon may occur.
The Premounted Stent System should be withdrawn until the proximal end of the stent is aligned with the distal tip of the introducer sheath. The introducer sheath and Premounted Stent System should be removed as one unit.

Deployment Procedure
1. To deploy the stent, slowly inflate the Premounted Stent System to at least the opening pressure shown in Table 1 using an inflation device. Higher pressure may be necessary to optimize apposition against the stricture. Balloon pressures must not exceed rated burst pressure 12 atm (1216 kPa).

Note: It is strongly recommended that the guidewire remain across the stricture until the procedure is complete.

2. After deploying the stent, deflate the balloon by pulling negative pressure on inflation device until balloon is fully deflated.

Caution: Allow adequate time for the balloon to fully deflate prior to removal. Observe fluoroscopically that the balloon is fully deflated.

3. Maintaining proper introducer sheath support, very slowly withdraw the balloon. Observe under fluoroscopy to ensure that the balloon disengages from the stent.

Caution: If resistance is encountered upon attempted removal, do not force removal, use fluoroscopy and conventional techniques to determine and remedy the cause of resistance before proceeding.

4. Confirm stent position and deployment using fluoroscopic techniques. For optimal results, the entire stricture should be covered by the stent. Fluoroscopic visualization should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal reference duct diameter.

5. If re-sizing is necessary, re-advance the SDS, or another balloon catheter of appropriate size, to the stented area using conventional techniques.

6. While observing under fluoroscopy, inflate the balloon to the desired pressure; do not exceed the rated burst pressure. Do not expand the stent beyond maximum stent diameter as shown in Table 1. Deflate the balloon and follow the instructions as outlined in step 3 above.

7. Reconfirm stent position and fluoroscopic result. Repeat inflations until the desired result is achieved.

8. While maintaining negative pressure in the balloon, remove the SDS from the body and through the introducer sheath.

Table 2. Typical Express® LD Biliary Premounted Stent System Compliance

Pressure (atm-kpa)	Balloon Diameter (mm)					
	5.0 mm	6.0 mm	7.0 mm	8.0 mm	9.0 mm	10.0 mm
6 - 608	N/A	5.79	6.69	7.60	8.67	9.57
7 - 709	4.66	5.83	6.76	7.70	8.75	9.69
8.0 – 811*	4.72*	5.89*	6.85*	7.83*	8.87*	9.80
9.0 - 912	4.77	5.97	6.93	7.92	8.93	9.88
10.0 - 1013*	4.83	6.02	6.99	7.99	9.00	9.97*
11 - 1115	4.88	6.08	7.04	8.05	9.05	10.03
12 – 1216**	4.92	6.11	7.08	8.10	9.10	10.08
*Nominal Pressure						
**Rated Burst Pressure. DO NOT EXCEED.						
User should confirm stent diameter angiographically during balloon inflation.						

WARRANTY:
Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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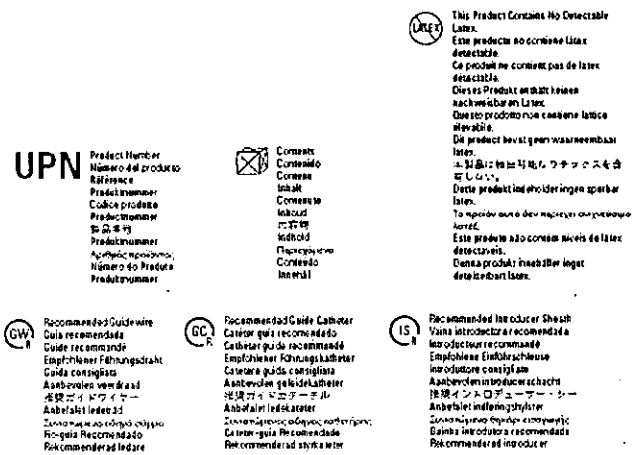

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